HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service M2134

Food and Drug Administration
New Orleans District
Southeast Region
4298 Elysian Fields Avenue
New Orleans, Louisiana 70122-3896

Telephone: 504-589-6341
Fax: 504-589-6360

October 27, 1998

WARNING LETTER NO. 98-NOL-05

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Edward T. Lee, President
Hontex Enterprises, Inc. d.b.a.
Louisiana Packing Company
501 Louisiana Street
Westwego, Louisiana 70094-4141

Dear Mr. Lee:

During the July 28-30, 1998, inspection of your seafood processing facility, located at 501 Louisiana Street, Westwego, Louisiana, it was documented that your firm is not in compliance with the Food and Drug Administration's seafood processing regulations. Based on the FDA inspections, the products are adulterated under Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act in that the processor failed to operate in accordance with the requirements of Title 21 Code of Federal Regulations (21 CFR) Part 123 "Safe and Sanitary Processing and Importing of Fish and Fishery Products."

1. Your firm's HACCP Plan is inadequate for cooked, peeled shrimp in that:
   a. There is no documentation of the establishment of the cooking process parameters;
   b. It does not specify a correct procedure for monitoring the continuous cooker temperature nor the time of cook;
   c. It does not identify the individual responsible for monitoring critical control points during the cooking operation;
   d. It does not include calibration of instruments used for monitoring time and temperature;
   e. It does not include sulfites as a hazard; and,
   f. It does not include critical limits associated with control of cooked product process time.

2. Your firm failed to take corrective actions when product was found to have deviated from, or exceeded the critical limit specified in the HACCP plan [21 CFR § 123.7(a)]. In this instance, your firm failed to take corrective action when records revealed that product had been improperly processed;

3. Your firm failed to maintain adequate monitoring records for the critical control point (i.e., weight/pack/label) associated with the sulfite hazard [21 CFR § 123.6(c)(7)];

4. Sanitation monitoring records show inadequate information and missed sanitation checks. For example, sanitation monitoring records do not have the firm name and address and do not show the times that sanitation checks were made. Routinely, sanitation checks were missed because processing had already begun;

5. Your firm failed to have and implement a HACCP plan whenever a hazard analysis revealed one or more food safety hazards [21 CFR § 123.6(b)], specifically, for the re-work product;

6. Other poor manufacturing practices were evidenced by overcrowding and disorderly storage of finished product in two of three freezers, two unshielded freezer ceiling lights, gumbo crab packaging operation immediately adjacent to an opened, unscreened door, and tall, uncut vegetation approximately 30 feet from processing room and immediately adjacent to restroom facility; and,

7. There is no documentation that the requirements for importing Chinese crawfish tails were fulfilled. For example, there is no documentation of written verification procedures to include:
   a. Product specifications for the control of all possible food safety hazards known for crawfish; and,
   b. At least one affirmative step to verify that the product was produced under a HACCP plan.

Additionally, this inspection noted that your sanitation monitoring records do not include all eight areas specified in 21 CFR §123.11(b) of the Regulations. Specifically, the areas not included are: 1) safety of the water; 2) prevention of cross-contamination; 3) maintenance of hand washing facilities; 4) protection of food from contamination; 5) proper labeling, storage and use of toxic compounds; 6) control of employee health conditions; and, 7) exclusion of pests.

The above identification of violations is not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of FDA's Seafood Processing Regulations and the Good Manufacturing Practice Regulations.

You should take prompt action to correct these deviations. Failure to correct these deviations may result in regulatory action without further notice. This may include seizure and/or injunction. This letter serves as official notice that FDA expects all your firms to be in compliance.

You should notify this office in writing, within 15 working days of receipt of this letter of the steps that you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action can not be completed within 15 working days, state the reason for this delay, and the time within which the corrections will be completed.

Your response should be directed to Nicole F. Hardin, Compliance Officer, Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana 70122-3896. Should you have any questions concerning the contents of this letter or if you desire a meeting with the Agency staff, do not hesitate to contact Ms. Hardin.

Sincerely

James E. Gamet
District Director
New Orleans District Office

Enclosure: FDA-483